



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
PO Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/939,833 | 08/28/2001 | Michele A. McTigue | 0125-0016D1 | 3848 |

28940 7590 08/12/2003

AGOURON PHARMACEUTICALS, INC.
10350 NORTH TORREY PINES ROAD
LA JOLLA, CA 92037

| |
|----------|
| EXAMINER |
|----------|

KIM, YOUNG J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

9

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|------------------------|---------------------|
| Offic Action Summary | Application N . | Applicant(s) |
| | 09/939,833 | MCTIGUE ET AL. |
| | Examin r | Art Unit |
| | Young J. Kim | 1637 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17 and 18 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 17 and 18 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 13 November 2001 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. ____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

4) Interview Summary (PTO-413) Paper No(s). ____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____.

DETAILED ACTION

Preliminary Remark

The Office acknowledges the cancellation of claims 1-16 and the addition of claims 17 and 18.

Claims 17 and 18 are pending and are under prosecution therefore.

Specification

Sequence Rules

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 CFR 1.82(a)(1) and (a)(2). However, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825. For example, page 10 of the specification alludes to two additional primers sequence to which the SEQ ID Numbers are missing (5th paragraph). See also the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures.

A fully responsive communication will fulfill the sequence rules.

Claim Objections

Claim 18 is objected to because of the following informalities:

Claim 18 recites the acronym, "VEGFR," without first identifying it. Amending the claim to recite the phrase, "Vascular Endothelial Growth Factor Receptor," would obviate this objection.

Appropriate corrections are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (U.S. Patent No. 6,043,211, issued March 28, 2000, filed June 5, 1995).

Claim is drawn to a modified RTK polypeptide, wherein said modified RTK polypeptide comprises truncated Kinase Insert Domain (KID).

Williams et al. disclose a modified PDGFR- β (or RTK polypeptide) (column 2, lines 20-28; column 6, lines 5-10; column 46, lines 20-28; claim limitation 17). The modified PDGFR- β is interacted with PI3 kinase, wherein said modified PDGFR- β comprises deletion of the kinase insert (KI) region (or Kinase Insert Domain) (column 46, lines 23-25; claim limitation 17).

Williams et al. discloses that direct structural determination via x-ray crystallography or 2D-NMR can be used to determine locations of interactions, which guide where the modifications are likely to affect interactions, both ligand and effector binding activities (column 30, lines 60-65), demonstrating that the polypeptide is suitable for x-ray crystallography (claim limitation 17). The modified polypeptide is disclosed as retaining its tyrosine kinase acitivity, evidencing that the kinase domain is of sufficient length to maintain conformation associated with kinase structure (column 46, line25; claim limitation 17).

Since the modified PDGFR- β comprises a truncated kinase insert domain, absent evidence to the contrary, the polypeptide is determined to have the domain α helix D linked to α helix E. According to *In re Best* 195 USPQ 430, 1997, the court stated that, "Patent Office can require applicant to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product wherein claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicant" (pp. 430).

Therefore, the invention as claimed is obvious over the cited reference.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 18 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of copending Application No. 09/939,754, 09/939,832, and 09/939,833. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 7 of the '754, '832, and '833 applications are drawn to an isolated oligonucleotide coding the polypeptide of SEQ ID Number 5. Instant claim 18 is also drawn to the same.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/7/03



Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/11/03